

ACHIEVING BALANCE

in State Pain Policy

A Progress Report Card



Pain & Policy Studies Group

University of Wisconsin

Comprehensive Cancer Center

www.medsch.wisc.edu/painpolicy

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State policies aimed at preventing drug abuse and regulating professional practice can both enhance and interfere with pain management. A three-year evaluation by the University of Wisconsin Pain & Policy Studies Group shows improvement in state policies governing the medical use of opioid medications. This *Progress Report Card* grades states' policies from A to F. Along with a companion policy analysis (entitled *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation (Second edition)*), it can be used by state agencies and pain relief advocates to develop plans to further improve state pain policies.

The information used to create this *Progress Report Card* is based on a systematic evaluation of the best information available to the PPSG. We hope that our conclusions and recommendations will stimulate individuals, organizations, and state agencies to engage one-another to evaluate or re-evaluate their policies regarding pain management and take the necessary steps to improve and implement them. In this way, one important aspect of the pain problem can be addressed.

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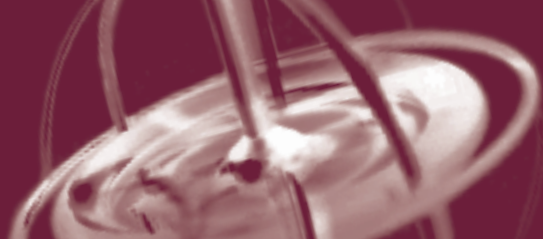
The Pain & Policy Studies Group

The mission of the Pain & Policy Studies Group is to achieve more balanced international, national and state policies so that patients' access to pain medications is not compromised by efforts to prevent diversion and drug abuse.

Recent contributions of the PPSG to improving pain management include the following publications, available at www.medsch.wisc.edu/painpolicy/biblio.htm:

- ◆ Workshops for members of state medical boards, and an evaluation that showed improvements in their knowledge and attitudes about pain management and public policy.
- ◆ Evaluation of state medical board guidelines, showing that state policies improved when boards used a model policy.
- ◆ Evaluation of federal and state policy, often used to guide state policy evaluation and development.
- ◆ Evaluation of federal and state policies on the use of controlled substances for treatment of pain in persons with a history of substance abuse.
- ◆ Description of a dialog between the pain and regulatory communities about prescription monitoring programs.
- ◆ Description of a state medical board's efforts to communicate new pain policies to physicians.
- ◆ Analysis of a decade of change in state pain policies.
- ◆ Update of trends in medical use and abuse of opioid pain medications.

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EXECUTIVE SUMMARY

People are often surprised that painful conditions go unrelieved in the U.S. The consequent suffering is tragic; it is also ironic, in light of existing knowledge about pain and its management. Pain, sometimes severe and debilitating, is associated with a variety of chronic diseases and conditions, including cancer, sickle cell disease, and HIV/AIDS. When pain is relieved there is improved quality of health and life. Unfortunately, inadequate management of pain occurs all too often.

Most if not all pain can be relieved if knowledgeable healthcare professionals use effective treatments, including opioid analgesics, when appropriate. There are many effective treatments for pain; opioid analgesics play an important role, especially when pain is moderate to severe. Unrelieved pain is usually due to barriers that interfere with the use of existing knowledge about pain and its treatment in everyday medical practice and patient care. There is a special set of policy-related barriers that interfere with the medical use of opioid analgesics. The focus of this report is on state policies that govern the medical use of opioid analgesics.

State policies govern the medical use of controlled substances to prevent their misuse, abuse, and diversion. When opioid analgesics are needed for patient care, these policies come into play and can interfere in medical practice. Efforts to improve state policies have resulted in positive changes, as well as unintended restrictions. This report grades each state on the extent that their policies contain language that potentially enhances or impedes pain management.

Based on policies in effect as of March 2003, 35% of states earned a grade of C, while 41% scored above a C and about a quarter fell below a C. No state received an A or F. Regional grade patterns were observed for central Midwest and western states. When compared to grades based on policies from three years earlier, 16 states evidenced positive policy change. A substantial amount of the change that occurred between 2000 and 2003 resulted from three primary sources: (1) state healthcare regulatory boards adopting policies encouraging pain management, palliative care, or end-of-life care, (2) the repealing of single- or multiple copy prescription programs, and (3) the rescinding of restrictive or ambiguous policy language.

Considerable positive development in state policy affecting pain management has taken place during the last decade. Although consistency in pain policy among the states is improving, it remains an elusive goal. This report represents one important part of that change. There is a continuing momentum for positive policy change that results from increasing recognition of the need to remove regulatory barriers and encourage appropriate treatment of pain. This is a balance that can be achieved if policymakers and advocates work together, use the central principle as a guide, and take advantage of the policy resources that are available. Continued cooperation between healthcare professionals and regulatory agencies will be essential to further progress. This *Progress Report Card*, used in conjunction with *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation (Second edition)*, provides an evaluative framework for developing balanced controlled substances and medical practice policy relating to pain management in a rational and systematic way.

ACKNOWLEDGMENTS, CITATION, NOTES TO READER



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This report may be quoted or reproduced in whole or in part for educational purposes and may be cited as:

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Notes to the Reader

This document is one product of the ongoing research program of the Pain & Policy Studies Group. Our purpose for making these data available is to promote education and policy change. However, their use for research purposes is limited to those who are affiliated with the Pain & Policy Studies Group, or by permission.

The results presented herein pertain to policies adopted through March 2003. Individuals interested in more current policy information, or in using these results to implement change, can contact our office at the address below.

This publication is available on CD-ROM and on our website at www.medsch.wisc.edu/painpolicy. Requests, comments, and suggestions can be directed to:

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INTRODUCTION

Unrelieved pain continues to burden Americans

It is well documented that unrelieved pain continues to be a serious public health problem for the general population in the United States.¹⁻⁸ This issue is particularly salient for children,⁹⁻¹² the elderly,¹³⁻¹⁵ minorities,¹⁶⁻²⁰ patients with active addiction or a history of substance abuse,²¹⁻²³ developmental disabilities,²⁴ as well as for those with serious diseases such as cancer,²⁵⁻²⁷ HIV/AIDS,^{10,28,29} or sickle cell disease.³⁰ Clinical experience has demonstrated that adequate pain management leads to enhanced functioning and increased quality of life, while uncontrolled pain contributes to disability and despair.

Pain can be relieved

There are many safe and effective drug and non-drug ways to manage pain, which vary according to the individual needs of the patient. However, there is a general medical and regulatory consensus that opioid^a analgesics are necessary to maintain public health;³¹ they often are the mainstay of treatment, particularly if pain is severe.^{25,27,32,33} Their use for the relief of a variety of chronic non-cancer pain conditions is also clinically beneficial, although more studies are needed to guide selection of patients and use of opioids.^{34,35}

The gap

Although medical science has learned a great deal about pain management in the last 20 years, not all of this knowledge has been incorporated into practice. Consequently, a gap exists between what is known about the medical management of pain and the actual practices of caregivers and healthcare institutions. Incomplete or inaccurate knowledge, and varying attitudes about pain and the use of opioid medications, can inhibit pain management.

Influence of drug abuse control policy

Opioid medications have a potential for abuse. Consequently, they and the healthcare professionals who prescribe, administer, or dispense them are regulated pursuant to federal and state controlled substances policies, as well as under state laws and regulations that govern professional practice.³⁶ Such policies are intended only to prevent drug abuse and substandard practice related to prescribing, but in some cases go well beyond the usual framework that governs controlled substances and professional practice policy and can negatively affect legitimate medical practices and create undue burdens on caregivers and patients.³⁷

Some state policies do not conform to, or conflict with, current standards of professional practice, by:

- ◆ limiting the amounts that can be prescribed and dispensed,
- ◆ requiring special government-issued prescription forms,
- ◆ restricting access to patients who have a history of substance abuse or with addictive disease, even if they also have pain,

^a The term opioid refers to natural and semi-synthetic derivatives of the opium poppy, as well as similar synthetic compounds that have analgesic or pain relieving properties because of their effects in the central nervous system. These include codeine, morphine, hydromorphone, hydrocodone, oxycodone and fentanyl. Opioids are often inappropriately referred to as narcotics, a legal term that is no longer used in medicine because it suggests that opioids relieve pain by inducing sedation; while sedation can be a side effect of opioids it is not the mechanism that produces pain relief.

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- ◆ using outdated language that confuses pain patients with people who have addictive disease,
- ◆ considering opioids to be a treatment of last resort, and
- ◆ suggesting that therapeutic use of opioids may hasten death.

In addition to the presence of potentially restrictive language, language that can enhance pain management is frequently absent from state policies. For example, some states do not recognize that controlled substances are necessary for the public health or that pain management is an integral part of the practice of medicine, which are policies that have been recommended by governmental authorities in controlled substances and medical practice policy.^{31,37-40}

The need to evaluate policy

International and national authorities, including the World Health Organization (WHO), the International Narcotics Control Board (INCB), the Institute of Medicine (IOM), the American Cancer Society (ACS), and the National Institutes of Health (NIH), have called attention to the inadequate treatment of pain and have concluded that it is due in part to drug abuse control policies that impede medical use of opioids.^b These authorities have recommended evaluation and improvement of pain policies. For example, following a review of the reasons for inadequate cancer pain relief, the INCB asked all governments in the world to:

“...examine the extent to which their health-care systems and laws and regulations permit the use of opiates for medical purposes, identify possible impediments to such use and develop plans of action to facilitate the supply and availability of opiates for all appropriate indications” (p. 17).⁴¹

The WHO has stated that better pain management could be achieved throughout the world if governments used evaluation guidelines to identify and overcome regulatory barriers to the availability and appropriate medical use of opioid analgesics.³²

In the U.S., the IOM Committee on Opportunities in Drug Abuse Research called for:

“...additional research on the effects of controlled substance regulations on medical use and scientific research. Specifically, these studies should encompass the impact of such regulations and their enforcement on prescribing practices and patient outcomes in relation to conditions such as pain...[and]... for patients with addictive disorders” (p. 259).⁴²

The IOM Committee on Care at the End of Life recommended:

“...review of restrictive state laws, revision of provisions that deter effective pain relief, and evaluation of the effect of regulatory changes on state medical board policies...” [and] “reform [of] drug prescription laws, burdensome regulations, and state medical board policies and practices that impede effective use of opioids to relieve pain and suffering” (p. 198, 267).²

The ACS recently stated that

“...additional and sustained efforts are needed to ensure that new barriers are not erected and that adequate pain relief for cancer patients is assured” (p. 3).⁴³

An NIH expert panel concluded that

“Regulatory barriers need to be revised to maximize convenience, benefit, and compliance...” (p. 15).⁵

^b The Agency for Healthcare Policy and Research is not included as an authoritative source because its clinical practice guidelines on acute pain (1992) and cancer pain (1994) have been withdrawn.



THE PROGRESS REPORT CARD

This *Progress Report Card*, approved for funding by the Robert Wood Johnson Foundation in May 2002, was developed in response to the need to evaluate state policies that affect pain management.^c It is a tool that can be used by government and non-government organizations to achieve more positive and consistent state policy on the use of controlled substances for pain management (acute, cancer, and non-cancer pain), palliative care, and end-of-life care, while not disturbing the underlying policy that opioid analgesics may only be provided for legitimate medical purposes by licensed healthcare practitioners in the course of their professional practice. The policy terms used in this report are defined in Table 1.

Table 1: Policy Terms

Policy research terms

“Pain policy” is federal or state policy that relates to pain management, in particular the use of opioid analgesics. Pain-specific policies directly address pain and its management. Pain-related policies indirectly affect pain management.

“Provision” is policy language that was identified as satisfying evaluation criteria.

“Positive provision” is a provision that has the potential to enhance pain management.

“Negative provision” is a provision that has the potential to impede pain management.

Policy types

“Law” is a broad term that refers to rules of conduct with binding legal force adopted by a legislative body and includes federal and state statutes and regulations. There are a number of laws relating to pain and its treatment.

“Regulation” is an official policy issued by an agency of the executive branch of government pursuant to statutory authority; regulations have binding legal force and are intended to implement the administrative policies of a statutorily created agency. Regulations govern professional conduct including the treatment of pain with controlled substances, and establish what conduct is or is not acceptable for those regulated by the agency, such as physicians, pharmacists, and nurses. Regulations may not exceed an agency’s statutory authority.

“Guideline” is a policy officially adopted by a government agency to express its attitude about a particular matter. While guidelines do not have binding legal force, they clarify standards of practice for those regulated by an agency. A number of state medical, pharmacy and nursing boards have issued guidelines regarding the medical use of opioids that define the conduct the board considers to be within professional practice.

Each state has been assigned a grade based on findings from two separate evaluations of federal and state pain policies in 2000 and 2003, published by the University of Wisconsin Pain & Policy Studies Group (PPSG), which are the first and second editions of *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation*.^{44,45} To determine the extent of progress in the last three years, states’ grades from 2003 are compared to their grades from 2000.

The *Progress Report Card* is the result of a systematic policy analysis, rather than a statement of a “position” about a state’s pain policies. The use of a single index to compare states is useful and can draw the attention of state policy-makers and healthcare professionals to the

^c Federal policy was not included in this report card because such policy does not regulate professional practice. Evaluation of federal policies is available in the *Evaluation Guide 2003*, at www.medsch.wisc.edu/painpolicy/eguide2003/index.html.

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need to evaluate and improve the regulatory policy environment for pain management.^d We recognize that a grade oversimplifies a state's policy environment. Therefore, we are making available detailed information about the statutes, regulations, and guidelines evaluated in each state in the companion *Evaluation Guide* 2003. In addition, the complete text of each state's pain-specific policies is available on the PPSG website at www.medsch.wisc.edu/painpolicy/matrix.

The central principle of balance

The *Progress Report Card* is based on evaluations of state pain policies that were guided by a central principle called *balance*, which is defined in Table 2. Balance should underlie all drug control policies so that they recognize that efforts to prevent abuse should not interfere in the medical use of opioid analgesics for patient care.

Table 2: The Central Principle of Balance

The central principle of balance represents a dual obligation of governments to establish a system of controls to prevent abuse, trafficking, and diversion of narcotic drugs while, at the same time, ensuring their medical availability.

Medical availability

- ◆ While opioid analgesics are controlled drugs, they are also essential drugs and are absolutely necessary for the relief of pain.
- ◆ Opioid analgesics should be accessible to all patients who need them for relief of pain.
- ◆ Governments must take steps to ensure the adequate availability of opioids for medical and scientific purposes, including:
 - empowering medical practitioners to provide opioids in the course of professional practice,
 - allowing them to prescribe, dispense and administer according to the individual medical needs of patients, and
 - ensuring that a sufficient supply of opioids is available to meet medical demand.

Drug control

- ◆ When misused, opioids pose a threat to society.
- ◆ A system of controls is necessary to prevent abuse, trafficking, and diversion, but the system of controls is not intended to diminish the medical usefulness of opioids, nor interfere in their legitimate medical uses and patient care.

(Adapted from Pain & Policy Studies Group. *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation, Second Edition*. Madison, WI: Pain & Policy Studies Group, University of Wisconsin Comprehensive Cancer Center; 2003)

Appendix A presents the international and national legal and medical authorities from whose published findings concerning public policy the PPSG has derived the central principle of balance.

The evaluation criteria

The PPSG developed 17 criteria based on the principle of balance. They are divided into two categories and are used to identify positive and negative provisions in all state statutes, regulations, and guidelines (see Table 3 for a list of the individual criteria).^e The state grades are a measure of the quality of state pain policy in relation to the principle of balance, and are based on the frequency of provisions that meet the evaluation criteria; the higher the grade, the more balanced are a state's policies regarding opioid availability and pain management.

^dThe adequacy of controls to prevent diversion and abuse of controlled substances is also a valid topic for the evaluation of policy. The purpose of this document is to evaluate policies affecting drug availability, medical practice, and pain management, rather than drug abuse prevention and control.

^eThe District of Columbia is treated as a state.

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Table 3: Criteria Used to Evaluate State Pain Policies

Positive provisions: Criteria that identify policy language with the potential to enhance pain management

1. Controlled substances are recognized as necessary for the public health
2. Pain management is recognized as part of general medical practice
3. Medical use of opioids is recognized as legitimate professional practice
4. Pain management is encouraged
5. Practitioners' concerns about regulatory scrutiny are addressed
6. Prescription amount alone is recognized as insufficient to determine the legitimacy of prescribing
7. Physical dependence or analgesic tolerance are not confused with "addiction"
8. Other provisions that may enhance pain management

Negative provisions: Criteria that identify policy language with the potential to impede pain management

9. Opioids are considered a treatment of last resort
10. Medical use of opioids is implied to be outside legitimate professional practice
11. The belief that opioids hasten death is perpetuated
12. Physical dependence or analgesic tolerance are confused with "addiction"
13. Medical decisions are restricted
 - 13.1 Restrictions based on patient characteristics
 - 13.2 Mandated consultation
 - 13.3 Restrictions regarding quantity prescribed or dispensed
14. Length of prescription validity is restricted
15. Practitioners are subject to additional prescription requirements
16. Other provisions that may impede pain management
17. Provisions that are ambiguous

This report does not review all types of policies states can adopt to improve patient access to adequate pain management. Some states have initiated legislative and regulatory activity that has the potential to impact pain management, which falls outside of this evaluation methodology. For example, Rhode Island adopted a "Pain Assessment Act" in 2002, mandating healthcare professionals and organizations to conduct periodic assessments of patients' pain levels. New Jersey also introduced "5th Vital Sign" legislation in 2000, requiring healthcare facilities to routinely monitor patients for pain.

This report expands on Last Acts'*Means to a Better End: A Report on Dying in America Today*⁵⁶ by making use of current policy data to grade state pain policies; in addition, our grading methodology is different. The Last Acts report concluded that state policymakers should revise policies governing the prescribing of pain medications and work to ensure that healthcare providers are not afraid to prescribe analgesics when needed.

Readers are referred to the *Evaluation Guide 2003*, a companion to this report, for a detailed discussion of the imperative to evaluate policy, the principle of balance, the evaluation criteria, the method used to evaluate state policies, and the text of the policy provisions that were identified in each state.

^f Last Acts is a national campaign to improve end-of-life care by a coalition of professional and consumer organizations. It believes in palliative care, managing pain, and making life better for individuals and families facing death.

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Two capsules are provided to elucidate the relevance of selected evaluation criteria.

Capsule 1: Fear of Regulatory Scrutiny **Evaluation Criterion #5**

Patients _____
“With everything that is out there with these medications, aren’t you and your license in danger from prescribing this kind of medicine?” (Statements from patients in a large university chronic pain program.)

Physicians _____
Some physicians report that concern about being investigated by regulatory and licensing agencies when prescribing opioid medications for patients, including those with cancer pain and chronic non-cancer pain, leads them to prescribe lower doses or quantities of pain medication and to authorize fewer refills.^{46,47}

Regulators _____
Some members of state medical boards that license and investigate physicians believe that prescribing of opioids to patients with chronic non-cancer pain should be discouraged or investigated.³⁹ Knowledge and attitudes of medical board members toward opioid prescribing appear to be improving.^{48,49}

Policies _____
In the last decade, approximately 30 state legislatures and medical boards have adopted policies to begin addressing physicians’ concerns about being investigated for legitimate prescription of opioid pain medications.

Conclusion _____
Despite a growing effort by policymakers and regulators, the fear of regulatory scrutiny remains a significant impediment to pain relief and will take years of further policy development, communication, and education to overcome.

Capsule 2: Confusion about Addiction-Related Terms **Evaluation Criteria #7 & #12**

Patients _____
“...I was openly accused of being an ‘addict’ and of falsely reporting chronic pain just to obtain prescription drugs.”⁵⁰
Some cancer patients refuse pain treatment for fear of becoming addicted.^{51,52}

Physicians and Pharmacists _____
Some physicians express concern that addiction or drug abuse will develop when prescribing to patients with cancer, or chronic non-cancer, pain.^{46,47} Some pharmacists lack knowledge of the crucial distinction between addiction, physical dependence, and tolerance.^{53,54}

Regulators _____
Although some state medical regulators do not understand the meaning of “addiction,” educational efforts have led to notable improvements in their knowledge of this concept.³⁹

Policies _____
In the last decade, approximately 24 state healthcare regulatory boards have adopted policies that correctly define addiction-related terms. Despite this progress, 18 states still have inaccurate definitions that would allow pain management to be confused with addiction.^{45,55}

Conclusion _____
Confusion about addiction leads to overestimation of its prevalence and is a significant impediment to pain relief. Recently-adopted state policies and improved knowledge of regulators are steps in the right direction; however, a much greater systematic effort will be needed to clarify policy and educate policy makers, healthcare practitioners and patients so that concerns about addiction are based on an accurate understanding of this disease and do not interfere with pain management.



METHOD TO ASSIGN GRADES

The PPSG used a two-step method for this analysis: (1) identify the positive and negative policy provisions in each state, and (2) assign grades.

- (1) Identification of provisions: The positive and negative provisions in state pain policies in 2000 had already been identified for the *Evaluation Guide 2000*. The PPSG updated its policy database in March 2003 using the methodology explained in the *Evaluation Guide 2003*. The criteria were then used to identify positive and negative provisions in policies current through 2003.
- (2) Grading: The grading method was established using the total number of positive and negative provisions identified from the *Evaluation Guide 2000*.^g Each provision was given equal weight. For 2000, the total number of positive provisions for all states ranged from 0 to 28; the average number of positive provisions per state was 5 and the standard deviation (the extent that the values deviate from the average) was 4. The range for negative provisions was 0 to 19, with an average of 4 and a standard deviation of 3; the averages and standard deviations were used to calculate the grades (see Table 4). The same grading system was then applied to the total number of positive and negative provisions identified for all states in the *Evaluation Guide 2003*.

Table 4: Grading System for Positive and Negative Provisions

Positive Provisions	Negative Provisions	Distribution
A	F	2 or more standard deviations above the average
B	D	Within 1 standard deviation above the average
C	C	Around the average
D	B	Within 1 standard deviation below the average
F	A	0 provisions

The separate positive and negative grades can be found in Appendix B and are averaged to arrive at a state's final grade; unless otherwise specified, the term "grade" refers to the final grade. Mid-point grades were calculated (B+, C+, D+), rather than rounding up or down, in an effort to reflect more precisely each state's unique combination of positive and negative provisions. For example, if a state received an A for positive provisions and a B for negative provisions, the final grade would be a B+.

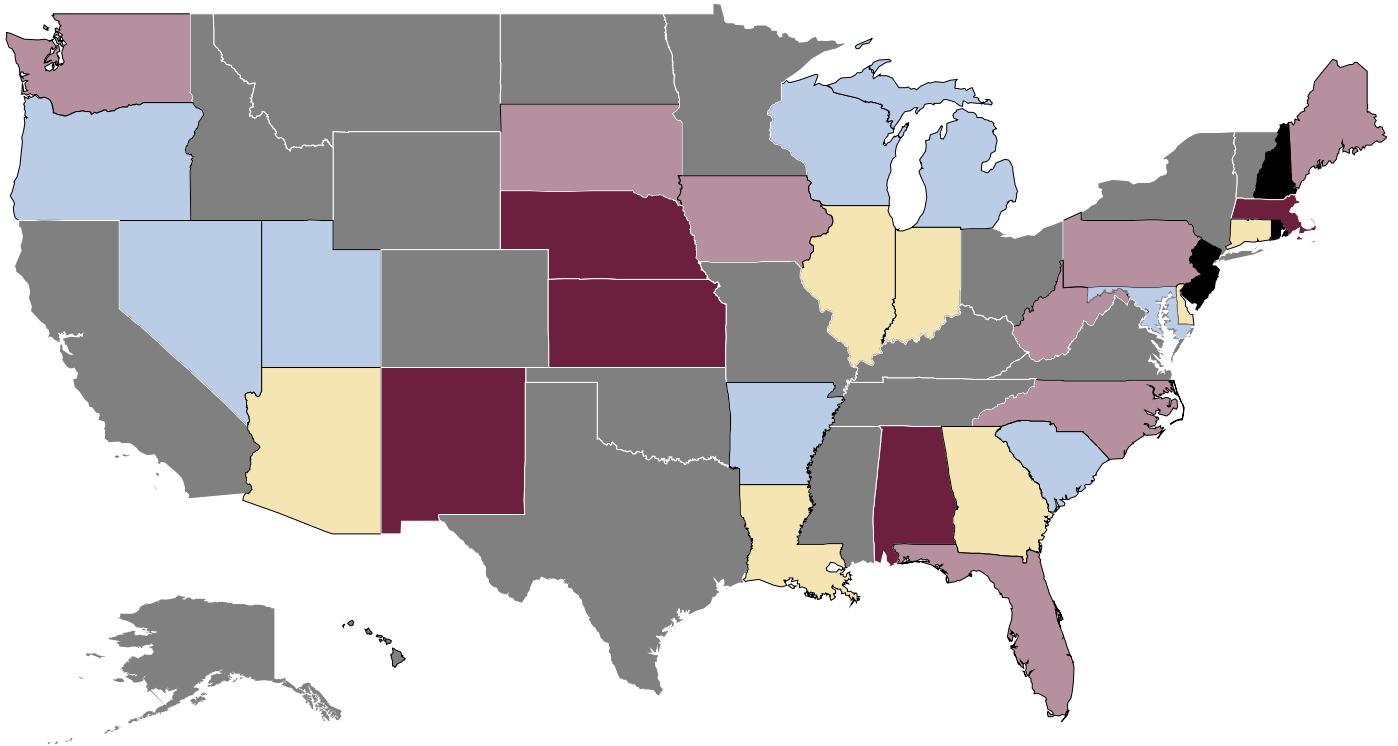
^g Grades for 2000 are based on revisions to the *Evaluation Guide 2000*.









MAKING THE GRADE: HOW DO THE STATES RATE?

Grades for 2003

Figure 1:

States' grades for 2003 are presented in Figure 1 and Table 5.



A 	B+ 	B 	C+ 	C 	D+ 	D 	F 
None	Alabama Kansas Nebraska Massachusetts New Mexico	Florida Iowa Maine North Carolina Pennsylvania South Dakota Washington West Virginia	Arkansas Maryland Michigan Nevada Oregon South Carolina Utah Wisconsin	Alaska California Colorado Idaho Kentucky Minnesota Mississippi Missouri Montana New York North Dakota Ohio Oklahoma Tennessee Texas Vermont Virginia Wyoming	Arizona Connecticut Delaware Dist. of Columbia Georgia Hawaii Illinois Indiana Louisiana	New Hampshire New Jersey Rhode Island	None

MAKING THE GRADE: HOW DO THE STATES RATE?

Table 5: State Grades for 2003

STATES	2003 GRADES	STATES	2003 GRADES
AL	B+	MT	C
AK	C	NE	B+
AZ	D+	NV	C+
AR	C+	NH	D
CA	C	NJ	D
CO	C	NM	B+
CT	D+	NY	C
DE	D+	NC	B
DC	D+	ND	C
FL	B	OH	C
GA	D+	OK	C
HI	D	OR	C+
ID	C	PA	B
IL	D+	RI	D
IN	D+	SC	C+
IA	B	SD	B
KS	B+	TN	C
KY	C	TX	C
LA	D+	UT	C+
ME	B	VT	C
MD	C+	VA	C
MA	B+	WA	B
MI	C+	WV	B
MN	C	WI	C+
MS	C	WY	C
MO	C		

Description of State Grades for 2003

- ◆ 35% of states scored around the average (thereby earning a grade of C), while 41% scored above the average and 24% fell below the average.
- ◆ No state received an A or F.
- ◆ A few regional patterns emerged: States in the central Midwest (Iowa, Kansas, Nebraska, and South Dakota) received Bs; the neighboring states of Illinois and Indiana, earned grades of D+; western states (California, Colorado, Idaho, Montana, Nevada, Oregon, Utah, and Wyoming) earned grades in the C range; the three states with the largest population (California, New York, and Texas) each earned average grades of C, owing to presence of policies containing many positive provisions but also a substantial number of negative provisions.

MAKING THE GRADE: HOW DO THE STATES RATE?

Changes from 2000 to 2003

To evaluate changes, either positive or negative, that occurred during the three-year period, 2003 grades were compared with the 2000 grades^h (see Table 6).

Table 6: State Grades, 2000 and 2003

STATES	2000 GRADES	2003 GRADES	STATES	2000 GRADES	2003 GRADES
AL	B+	B+	MT	C	C
AK	C	C	NE	B+	B+
AZ	D+	D+	NV	D	C+
AR	C+	C+	NH	D	D
CA	C	C	NJ	D	D
CO	C	C	NM	B	B+
CT	D+	D+	NY	C	C
DE	D+	D+	NC	B	B
DC	D+	D+	ND	C	C
FL	C+	B	OH	D+	C
GA	D+	D+	OK	C	C
HI	D	D+	OR	C+	C+
ID	D	C	PA	B	B
IL	D+	D+	RI	D	D
IN	D+	D+	SC	C	C+
IA	D+	B	SD	B	B
KS	B	B+	TN	D+	C
KY	D+	C	TX	C	C
LA	D+	D+	UT	C+	C+
ME	B	B	VT	C	C
MD	C+	C+	VA	C	C
MA	D+	B+	WA	B	B
MI	D+	C+	WV	C+	B
MN	C	C	WI	C	C+
MS	C	C	WY	C	C
MO	D	C			

Although no states received an A or F in either 2000 or 2003, a number of important changes occurred:

- ◆ 29% of states received above a C in 2000, increasing to 41% in 2003.
- ◆ 20 of 51 states (39%) changed their policies; the policy changes were sufficient in 16 of these states to produce a grade improvement.

^h 2000 grades were calculated to allow comparison and measure progress; see Method to Assign Grades section.

MAKING THE GRADE: HOW DO THE STATES RATE?

- ◆ Of the 16 states that improved, Massachusetts had the greatest improvement, moving from a D+ to a B+. This improvement was due to the Federation of State Medical Board's *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* (*Model Guidelines*). States that fully adopt the *Model Guidelines* received the greatest number of positive provisions (7) from a single policy, with no negative provisions:

- Criterion #2: Pain management is recognized as part of general medical practice,
- Criterion #3: Medical use of opioids is recognized as legitimate professional practice,
- Criterion #4: Pain management is encouraged,
- Criterion #5: Practitioners' concerns about regulatory scrutiny are addressed,
- Criterion #6: Prescription amount alone is recognized as insufficient to determine the legitimacy of prescribing,
- Criterion #7: Physical dependence or analgesic tolerance are not confused with "addiction," and
- Criterion #8: Other provisions that may enhance pain management.

Table 7 identifies the states with positive, negative, and no policy change.

Table 7: Grade Change in State Pain Policy Between March 2000 and March 2003

Positive Change (16 states)	No Change (35 states)
Florida Hawaii Idaho Iowa Kansas Kentucky Massachusetts Michigan Missouri Nevada New Mexico Ohio South Carolina Tennessee West Virginia Wisconsin	<div> Alabama Alaska Arizona Arkansas California Colorado Connecticut Delaware District of Columbia Georgia Illinois Indiana Louisiana Maine Maryland Minnesota Mississippi Montana Nebraska </div> <div> New Hampshire New Jersey New York North Carolina North Dakota Oklahoma Oregon Pennsylvania Rhode Island South Dakota Texas Utah Vermont Virginia Washington Wyoming </div>

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Reasons for the positive changes

The driving force behind the positive policy changes that occurred between 2000 and 2003 was state healthcare regulatory boards that adopted policies encouraging pain management or palliative care.

- ◆ Adoption of Model Guidelines: Six states (Kentucky, Massachusetts, Missouri, Nevada, New Mexico, and Texas) adopted healthcare regulatory policies based on the Federation of State Medical Board's *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* (*Model Guidelines*). States that fully adopt the *Model Guidelines* received the greatest number of positive provisions (7) from a single policy, with no negative provisions:

- Criterion #2: Pain management is recognized as part of general medical practice,
- Criterion #3: Medical use of opioids is recognized as legitimate professional practice,
- Criterion #4: Pain management is encouraged,
- Criterion #5: Practitioners' concerns about regulatory scrutiny are addressed,
- Criterion #6: Prescription amount alone is recognized as insufficient to determine the legitimacy of prescribing,
- Criterion #7: Physical dependence or analgesic tolerance are not confused with "addiction," and
- Criterion #8: Other provisions that may enhance pain management.

Twenty-two states have adopted the *Model Guidelines* either in whole or in part.ⁱ

- ◆ Adoption of Pharmacy Board Policies: Iowa adopted a pharmacy board policy statement relating to pain management, which added four positive provisions:

- Criterion #3: Medical use of opioids is recognized as legitimate professional practice,
- Criterion #4: Pain management is encouraged,
- Criterion #5: Practitioners' concerns about regulatory scrutiny are addressed, and
- Criterion #8: Other provisions that may enhance pain management.

- ◆ Adoption of Joint Board Policies: Three states (Kansas, Montana, and West Virginia) approved a joint policy statement relating to the use of controlled substances for the treatment of pain, which was developed collaboratively by several regulatory boards such as medicine, pharmacy, and nursing; collectively, the following positive provisions were added:

- Criterion #2: Pain management is recognized as part of general medical practice,
- Criterion #3: Medical use of opioids is recognized as legitimate professional practice,
- Criterion #4: Pain management is encouraged
- Criterion #5: Practitioners' concerns about regulatory scrutiny are addressed,
- Criterion #6: Prescription amount alone is recognized as insufficient to determine the legitimacy of prescribing,
- Criterion #7: Physical dependence or analgesic tolerance are not confused with "addiction," and
- Criterion #8: Other provisions that may enhance pain management.

ⁱ These states are Alabama, Arizona, Florida, Iowa, Kansas, Kentucky, Maine, Massachusetts, Missouri, Nebraska, Nevada, New Hampshire, New Mexico, New York, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, and West Virginia.

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- ◆ Adoption of Palliative Care Policies: The Missouri medical board adopted a palliative care guideline to educate physicians about the treatment of terminally-ill patients, adding two positive provisions:
 - Criterion #4: Pain management is encouraged, and
 - Criterion #8: Other provisions that may enhance pain management.

Positive policy change also occurred when states repealed negative provisions.

- ◆ Change in Prescription Monitoring Programs: Three states (Hawaii, Idaho, and Michigan) repealed their requirement for a multiple- or single-copy prescription form (Criterion #15) and replaced it with an Electronic Data Transfer system that does not require a special government-issued prescription form. Such a change is thought to eliminate a barrier to pain management because of reluctance to obtain and use the forms and by being a less intrusive method to monitor physicians' prescribing. Only three states (California, New York, and Texas) currently have a multiple- or single-copy prescription form requirement.
- ◆ Repeal of Restrictive Prescription Validity Periods: Four states modified overly restrictive prescription validity periods (Criterion #14) from controlled substances statutes and/or regulations:
 - Hawaii eliminated its 3 day period;
 - Michigan eliminated a 5 day period;
 - Wisconsin eliminated a 7 day period; and
 - Idaho extended its validity period from 7 days to 30 days.

This change eliminates the barrier of an unrealistically short validity period (i.e., the number of days within which the prescription must be dispensed following its issue), which can make it difficult for a patient to obtain medications without having to make sometimes expensive arrangements, especially when travel, slow mail delivery, or other extenuating circumstances exist. Exceeding a prescription's validity period necessitates issuance of a new prescription and a likely return visit to the physician. Seven states have retained a validity period of less than two weeks.^j

- ◆ Repeal of Mandated Consultation Provision: Three states (Iowa, Massachusetts, and Michigan) repealed provisions mandating that physicians always consult with pain specialists when using controlled substances to treat patients with pain (Criterion #13.2). Such provisions typically require a physician treating chronic non-cancer pain with opioids to obtain "...[an] evaluation by the attending physician and one or more physicians specializing in the treatment of the area, system, or organ of the body perceived as the source of the pain..."⁵⁷ Although there is no question that physicians should seek consultation when needed, such a requirement may not be necessary for every case, especially if the practitioner is knowledgeable about pain management. In addition, such a requirement does not appear to allow for patients who need immediate treatment. Eleven states continue to mandate consultation under certain circumstances when using opioids to treat patients with pain.^k

^j These states are California, Delaware, Illinois, Nevada, Rhode Island, Texas, and Vermont.

^k These states are Arizona, California, Colorado, Idaho, Mississippi, Nevada, New York, Ohio, Oregon, Rhode Island, and Vermont.

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Despite this positive change, a few states added more restrictive provisions.

- ◆ Adoption of Hastening Death Provisions: Ohio and Rhode Island added language that perpetuates the misconception that the therapeutic use of opioids to relieve pain in patients at the end of life hastens death (Criterion #11). For example, Rhode Island added statutory language that provides immunity from criminal prosecution to “A licensed health care professional who administers, prescribes or dispenses medications or procedures to relieve another person’s pain or discomfort, even if the medication or procedure may hasten or increase the risk of death...”⁵⁸ While the intent of the policy as a whole is to encourage pain management, it reinforces an unfounded fear about opioids⁵⁹ that can itself contribute to inadequate treatment of pain. Such a provision is now present in 15 states.¹
- ◆ Adoption of Provisions Mandating Opioids as Treatment of Last Resort: Kentucky and Montana added provisions mandating that a physician always document that other treatment measures and drugs have been inadequate or not tolerated before beginning a regimen of controlled substances, suggesting that medical use of opioids is considered, as a matter of policy, a treatment of last resort (Criterion #9). Kentucky’s new provision is as follows: “Before beginning a regimen of controlled drugs, the physician must determine, through actual clinical trial or through patient records and history that non-addictive medication regimens have been inadequate or are unacceptable for solid clinical reasons.”⁶⁰ Currently, 9 states have policies that consider opioids to be a treatment of last resort.^m
- ◆ Adoption of Intractable Pain Treatment Acts: Tennessee adopted an Intractable Pain Treatment Act (IPTA)⁶¹ containing a number of restrictive or ambiguous provisions, such as implying opioids are a treatment of last resort (Criterion #9) and their use is outside legitimate professional practice (Criterion #10), and confusing “addiction” with physical dependence or tolerance (Criterion #12). As of March 2003, 11 states have adopted IPTAs containing restrictive provisions.ⁿ

¹ These states are Iowa, Indiana, Kansas, Kentucky, Maryland, Michigan, Minnesota, New Hampshire, Ohio, Oklahoma, Rhode Island, South Carolina, South Dakota, Tennessee, and Virginia.

^m These states are Arizona, Georgia, Kentucky, Louisiana, Mississippi, Montana, Ohio, Tennessee, Virginia, and West Virginia.

ⁿ These states are California, Colorado, Minnesota, Missouri, North Dakota, Oregon, Rhode Island, Tennessee, Texas, and West Virginia.



CONCLUSIONS

Since 2000, legislatures and agencies in 16 states have modified their laws, regulations, or guidelines sufficiently to improve their grade for balanced policy. States added a number of provisions aimed at improving pain management and removed some provisions with the potential to interfere with medical practice. Several states adopted pain-related policies that also contained additional restrictions that can impede patient access to pain care. Overall, the modifications amount to excellent progress for a three-year period, but they do not take into account the extensive changes in pain policy that occurred throughout the 1990s.

Indeed, prior to 2000, a number of states adopted the *Model Guidelines* and other policies on pain management, palliative care, and end-of-life care. The *Model Guidelines* and the *Evaluation Guide 2000* continue to demonstrate their value as a template for evaluating and modifying pain policy. Several states also repealed the requirement for physicians and pharmacists to use government-issued prescription forms, substituting electronic prescription monitoring programs. Many of the positive policy changes that occurred between 2000 and 2003 were due to the adoption by state regulatory boards of policies encouraging pain management or palliative care. Some of the driving forces were state pain initiatives and end-of-life care coalitions that have been active in influencing state policies.^{56,62,63}

Achieving balance and consistency in pain policy among the states remains an elusive goal because many negative provisions remain. Table 8 shows the number of states with statutes, regulations, or guidelines that contain language meeting criteria for negative provisions.

Table 8: Number of States with Policy Language Having Potential to Impede Pain Management

Negative provisions	Number of states
9. Opioids are considered a treatment of last resort	9
10. Medical use of opioids is implied to be outside legitimate professional practice	14
11. The belief that opioids hasten death is perpetuated	15
12. Physical dependence or analgesic tolerance are confused with “addiction”	18
13. Medical decisions are restricted	
13.1 Restrictions based on patient characteristics	5
13.2 Mandated consultation	11
13.3 Restrictions regarding quantity prescribed or dispensed	10
14. Length of prescription validity is restricted	7
15. Practitioners are subject to additional prescription requirements	3
16. Other provisions that may impede pain management	15
17. Provisions that are ambiguous	33

CONCLUSIONS

It is recognized that states may enact laws or other governmental policies that are more strict than federal law. We respect the right of states to experiment and differ in their approaches to public policy, but it is necessary to ensure that all such policies are balanced and that patient care decisions requiring medical expertise are not predetermined by governmental regulation. This concept was recognized by the WHO Expert Committee on Cancer Pain Relief and Active Supportive Care:

“...governments have the right to impose further restrictions if they consider it necessary, to prevent diversion and misuse of opioids. However, this right must be continually balanced against the responsibility to ensure opioid availability for medical purposes...” (p. 56).²⁷

Overall, the momentum for positive change in state policy continues into 2003, apparently in response to increasing national recognition of the need to improve pain management and remove policies that conflict with pain management, professional practice, and patient care. Such progress is distinguished by knowledge-based policy development, in which current medical standards of medication use and pain management are understood and used to create positive public policy. This trend continues during a period of increase in both the medical use and abuse of opioid pain medications.^{64,65} In the future, it will be important that efforts by governments and healthcare professionals to address drug abuse not interfere with legitimate medical practices and patient access to pain care. This is a balance that can be achieved if policymakers and advocates work together, use the central principle of balance as a guide, and take advantage of the policy resources that are available; our contribution to this process is policy research, model development, and technical assistance to agencies and professionals.



RECOMMENDATIONS: HOW TO IMPROVE YOUR STATE'S GRADE

1. Evaluate and reform. Legislatures, professional licensing boards, and healthcare organizations are encouraged to evaluate and modify their state pain policies. In some states, ad hoc activities to improve public policy addressing pain management, end-of-life care and palliative care have been established, including task forces, commissions, advisory councils and summit meetings.^{56,62,66} To achieve more balanced policy, states will need to remove restrictive or ambiguous language as well as adopt positive policies. Repeal of negative provisions is particularly important in those states that already have policies containing many positive provisions. Each state's updated policy profile is provided in *Evaluation Guide 2003* to enable identification of specific policy language in need of reform. *Evaluation Guide 2003* also contains Models for Change, a review of positive policies that can be adopted, in particular the *Model Guidelines*. In addition, the ACS has produced a *Toolkit* that provides concrete suggestions for achieving balanced pain policies that can benefit all patients with pain.⁶⁷

2. Implement. Policy change with no implementation has little value. Legislatures, professional licensing boards, and healthcare groups should disseminate new policies widely and repeatedly. Once a state's policies have been improved, they should be communicated to those who implement policy, including administrators, investigators, attorneys, as well as to licensees and the public. The goal is to promote broad understanding that it is the state's policy to prevent drug abuse *and* to encourage pain management, and that healthcare professionals who provide controlled substances responsibly have nothing to fear from regulatory agencies in the state. For example, the medical licensure boards in North Carolina and Minnesota have excelled in their efforts to communicate pain management policy to licensed physicians.⁶⁸⁻⁷⁰ The Maryland Board of Physician Quality Assurance has produced a videotape titled "A Sense of Balance: Treating Chronic Pain,"⁷¹ which is required viewing for new licensees.

3. Cooperate. Healthcare professionals should work with regulators and policymakers to evaluate and reform state pain policies.^{36,72} Regulatory agencies already have a track record of working with health professionals to achieve the progress described in this report, including the Drug Enforcement Administration,⁷³ state medical, pharmacy and nursing boards,⁷⁴ and prescription monitoring programs.⁷⁵ Cooperation between healthcare professionals, law enforcement, and regulatory agencies will be essential to further progress.

APPENDIX A: Authoritative Sources for the Central Principle of Balance

International sources

Single Convention on Narcotic Drugs of 1961 (United Nations, 1977):

“the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering...adequate provision must be made [by governments] to ensure the availability of narcotic drugs for such purposes” (p. 13).

“The Parties [national governments] shall take such legislative and administrative measures as may be necessary...to limit exclusively to medical and scientific purposes the production, manufacture...distribution... and possession of drugs” (p. 18-19).

World Health Organization:

“Decisions concerning the type of drug to be used, the amount of the prescription and the duration of therapy are best made by medical professionals on the basis of the individual needs of each patient, and not by regulation” (WHO, 1996, p. 58).

“those [drugs] that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage forms...” (WHO Expert Committee on Essential Drugs, 1998, p. 2).

“These [Evaluation] Guidelines can be used by governments to determine whether their national drug control policies have established the legal and administrative framework to ensure the medical availability of opioid analgesics, according to international treaties and the recommendations of the INCB and the WHO... [and] to encourage governments to achieve better pain management by identifying and overcoming regulatory barriers to opioid availability” (WHO, 2000, p. 1-2).

(1) United Nations. Single Convention on Narcotic Drugs, 1961, As Amended by the 1972 Protocol Amending the Single Convention on Narcotic Drugs, 1961. New York, NY: United Nations; 1977.
(Available at http://www.incb.org/e/ind_conv.htm).

(2) World Health Organization. The Use of Essential Drugs: Eighth Report of the WHO Expert Committee (Technical Report Series 882). Geneva, Switzerland: World Health Organization; 1998.

(3) World Health Organization. Cancer Pain Relief: With a Guide to Opioid Availability. Second ed. Geneva, Switzerland: World Health Organization; 1996.
(Available at <http://whqlibdoc.who.int/publications/9241544821.pdf>).

(4) World Health Organization. Achieving Balance in National Opioids Control Policy: Guidelines for Assessment. Geneva, Switzerland: World Health Organization; 2000.
(Available at <http://www.medsch.wisc.edu/painpolicy/publicat/00whoabi/00whoabi.htm>).

National sources

Controlled Substances Act:

“Many of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people” (Title 21 Controlled Substances Act §801(1)).

Drug Enforcement Administration:

“This section is not intended to impose any limitations on a physician or authorized hospital staff to...administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts” (Title 21 Code of Federal Regulations §1306.07(c)).

“The CSA requirement for a determination of legitimate medical need is based on the undisputed proposition that patients and pharmacies should be able to obtain sufficient quantities...of any Schedule II drug, to fill prescriptions. A therapeutic drug should be available to patients when they need it...” (53 Federal Register 50593, 1988).

“Preventing drug abuse is an important societal goal, but there is consensus, by law enforcement agencies, health care practitioners, and patient advocates alike, that it should not hinder patients’ ability to receive the care they need and deserve...Undertreatment of pain is a serious problem in the United States, including pain among patients with chronic conditions and those who are critically ill or near death. Effective pain management is an integral and important aspect of quality medical care, and pain should be treated aggressively...For many patients, opioid analgesics – when used as recommended by established pain management guidelines – are the most effective way to treat their pain, and often the only treatment option that provides significant relief... Drug abuse is a serious problem. Those who legally manufacture, distribute, prescribe and dispense controlled substances must be mindful of and have respect for their inherent abuse potential. Focusing only on the abuse potential of a drug, however, could erroneously lead to the conclusion that these medications should be avoided when medically indicated – generating a sense of fear rather than respect for their legitimate properties” (Drug Enforcement Administration, Last Acts et al. 2001).

APPENDIX A: Authoritative Sources for the Central Principle of Balance (continued)

National sources (continued)

Federation of State Medical Boards of the U.S. (1998):

“principles of quality medical practice dictate that the people...have access to appropriate and effective pain relief...physicians [should] view effective pain management as a part of quality medical practice for all patients with pain...All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances...controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins” (p. 1).

“Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agency for prescribing, dispensing, or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice” (p. 2).

National Association of Attorneys General (2003):

“The National Association of Attorneys General encourages states to ensure that any such programs or strategies implemented to reduce abuse of prescription pain medications are designed with attention to their potential impact on the legitimate use of prescription drugs” (p. 2).

(1) Controlled Substances Act. Pub L No. 91-513, 84 Stat 1242, 1970.

(2) Drug Enforcement Administration, Last Acts, Pain & Policy Studies Group, et al. *Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act*. Washington, DC: Last Acts; 2001. (Available at <http://www.medsch.wisc.edu/painpolicy/dea01.htm>).

(3) Federation of State Medical Boards of the United States Inc. *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*. Euless, TX: Federation of State Medical Boards of the United States Inc; 1998. (Available at <http://www.fsmb.org>).

(4) National Association of Attorneys General. *Resolution Calling for a Balanced Approach to Promoting Pain Relief and Preventing Abuse of Pain Medications*. Adopted at the National Association of Attorneys General Spring Meeting; Washington, DC; March 17-20, 2003.

APPENDIX B: State Grades for Positive and Negative Provisions, 2000 and 2003

STATES	(+) GRADE 2000	(+) GRADE 2003	(-) GRADE 2000	(-) GRADE 2003
AL	B	B	A	A
AK	F	F	A	A
AZ	D	D	C	C
AR	C	C	B	B
CA	A	A	F	F
CO	B	B	D	D
CT	D	D	C	C
DE	D	D	C	C
DC	F	F	B	B
FL	B	A	C	C
GA	D	D	C	C
HI	F	F	C	B
ID	D	D	D	B
IL	F	F	B	B
IN	D	D	C	C
IA	D	B	C	B
KS	B	A	B	B
KY	D	B	C	D
LA	D	D	C	C
ME	C	C	A	A
MD	C	C	B	B
MA	D	D	C	B
MI	C	C	D	B
MN	C	C	C	C
MS	C	C	C	C
MO	C	A	F	F
MT	D	C	B	C
NE	A	A	B	B
NV	D	A	D	D
NH	F	F	C	C
NJ	D	D	D	D
NM	B	A	B	B
NY	A	A	F	F
NC	B	B	B	B
ND	C	C	C	C
OH	D	C	C	C
OK	B	B	D	D
OR	B	B	C	C
PA	B	B	B	B
RI	C	C	F	F
SC	B	B	D	C
SD	B	B	B	B
TN	B	A	F	F
TX	A	A	F	F
UT	B	B	C	C
VT	D	D	B	B
VA	C	C	C	C
WA	B	B	B	B
WV	B	A	C	C
WI	D	D	B	A
WY	D	D	B	B



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